REMARKS

Applicants respectfully request reconsideration and withdrawal of the rejections set forth in the Office Action. As requested by the examiner, paragraphs 0019, 0020, 0024, and 0098 of the specification were amended to reference the correct figures and to place the paragraphs in proper form.

Claims 1- 11 were pending in the above reference application. Claims 1 and 9 have been amended. Claims 6-8 are withdrawn from consideration. Additionally, applicants have added new claim 12. Exemplary support for this new claim exists in the specification at page 10, paragraph 43; and page 24, paragraph 77.

Because the foregoing amendments and new claims do not introduce new matter, entry there of by the examiner is respectfully requested. Upon entry of these changes, claims 1-5, and 9-12 will be pending in the application.

Rejection of Claims under 35 USC §112

Claims 1-5 and 9-11 are rejected under 35 USC §112, first paragraph, for lack of enablement and 35 USC §112, second paragraph, for indefiniteness. Applicants traverse these grounds for rejection.

Amended claims 1-5 identify a specific location on a specific gene as the GLP-2R promoter region, which should address the examiner's stated concerns regarding the prior art and §112 rejections, respectively.

The amended claims recite the location for the promoter region as "at least 1,000 nucleotides upstream of the transcription start site of the 5' untranslated region on the GLP-2R gene," which is amply supported in the specification on page 10, paragraphs 43 and 44; page 24, paragraphs 77 and 78; page 31, paragraphs 100 and 101; and page 46, paragraphs 153 and 154 .

New claim 12 covers a human GLP-2R promoter region by providing its location upstream of the transcription start site and a 126 bp sequence encoding a unique 41-aa N-terminal moiety as described in the specification on page 24, paragraphs 77 and 78.

Additionally, Applicants' respectfully disagree with the examiner's determination that the specification failed to provide an enabling disclosure. Using *Regents of the University of*

California v. Eli Lilly & Co., the examiner determined that the specific nucleotide sequence of the GLP-2R promoter region is required for the disclosure to be enabling. Applicants disagree with the examiner's interpretation of *Lilly*.

In the *Lilly* case, the challenged specification, in support of a claim to a "plasmid" coding for a "vertebrate mRNA reverse transcript of insulin," invoked: (A) a human proinsulin amino acid sequence, (B) a rat cDNA sequence for proinsulin, and (C) a general method for isolating cDNAs. The court deemed this disclosure insufficient to enable the claimed DNA because the description of the rat cDNA sequence for proinsulin and a generic method for isolating cDNA did not enable the claimed genera of "vertebrate" cDNAs (claim 2) and "mammalian" cDNAs (claims 4 and 5), respectively.

Thus, the patent owner in *Lilly* had provided nucleotide-sequence information only for the rat proinsulin cDNA and yet had claimed both "vertebrate" and "mammalian" cDNAs, all without teaching any element of proinsulin cDNA structure that was common to rat and other members in the "vertebrate" genus or the "mammalian" genus.

By contrast, the present application describes a similar location on the GLP-2R genes for the mouse, rat and human GLP-2R promoter regions. In addition, the specification discloses the similarity between portions of the mouse, rat, and human GLP-2R promoter region sequences. For instance, a comparison of the first 104 bp 5' to the initiator codon revealed a 96% identity between the mouse and rat sequences and a 76% identity between the mouse and human sequences as disclosed in the specification on page 31, paragraph 101. Further, figure 2 aligns the cloned 5' ends of the GLP-2R cDNAs of the mouse and rat. Additionally, the present specification on page 24, paragraphs 77 and 78, discloses that both the rat and the human promoter region sequences contain a 126-bp sequence encoding a unique 41-aa N-terminal moiety and separating the first and second transcriptional start site.

Accordingly, the present application passes muster under the *Lilly* analysis because it ***does*** evidence a structural similarity that typifies the recited "GLP-2R gene promoter region" genus, as illustrated by the disclosed mouse, rat and human GLP-2R promoter sequences. By the same token, there is no sustainable basis under Section 112 for rejecting the claims, under *Lilly* or any other existing case law.

Conclusion

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner also is invited to contact the undersigned, should any issue require further consideration.

Respectfully submitted,

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